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PATENT

Case Docket No.: 99,308

ASSISTANT COMMISSIONER FOR PATENTS

Patent Application

Washington, D. C. 20231

Date: January 21, 2000

Sir:

Transmitted herewith for filing is the patent application of:

Inventor: Thomas G. Stoll & Karl P. Schmidt

For: DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM

Enclosed are:

- X Abstract of the Disclosure (1 page) and
- 28 Pages of Specification and Claims
- 3 Sheets of drawings
- X Information Disclosure Statement
- X Verified statement(s) to establish small entity status under 37 C.F.R. 1.9 and 37 C.F.R. 1.27
- X The filing fee has been calculated as shown below:

FOR	NO. FILED	NO. EXTRA	SMALL ENTITY		OTHER THAN A SMALL ENTITY	
			RATE	FEE	RATE	FEE
BASIC FEE	*****	*****	****	\$ 345	or ****	\$ 690
TOTAL CLAIMS	19 - 20 = 0		x 9=	\$ 0	or x18=	\$
INDEP. CLAIMS	3 - 3 = 0		x39=	\$ 0	or x78=	\$
MULTIPLE DEPENDENT CLAIM PRESENTED			+130	\$ 0	or +260=	\$
			TOTAL	\$ 345	or TOTAL	\$

- X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 12-1660. A duplicate copy of this sheet is attached.
- X Our check No. 12622 is also enclosed to cover, among other items, the above filing fee.

Respectfully submitted,

LITMAN, KRAAI & BROWN, L.L.C.

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VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS
BY INVENTOR

Application: Thomas G. Stoll et al

Serial No.:

Filed: January 21, 2000

For: DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM

As a below-named inventor, in hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9 (c) for purposes of paying reduced fees under Section 41 (a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the above-entitled invention described in:

- (x) the specification filed herewith.
() application Serial No. _____, filed _____.

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who, upon knowledge and belief, could not be classified as an independent inventor under 37 C.F.R. 1.9 (c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9 (d) or a nonprofit organization under 37 C.F.R. 1.9 (e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation or under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

Name of Concern: NextMed, L.L.C.
Address of Concern: 1100 Main St. Suite 2001
Kansas City, Missouri 64105

I acknowledge my duty to file, in this application or patent, notification of any charges in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance

fee due after the date on which status as a small entity is no longer appropriate.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

1/19/20
Date

Thomas G. Stoll
Thomas G. Stoll

1/19/2000
Date

Karl P. Schmidt
Karl P. Schmidt

Express Mail EL300242708US

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS
BY SMALL BUSINESS CONCERN

Applicant: Thomas G. Stoll et al

Serial No:

Filed: January 21, 2000

For: DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM

I hereby declare that I am an official of a small business concern and am empowered to act on behalf of the concern identified below:

Name of Concern: NextMed, L.L.C.
Address of Concern: 1100 Main St. Suite 2001
Kansas City, Missouri 64105

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41 (a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. (For purposes of this state, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly, or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.)

I hereby declare that exclusive rights to the invention have been conveyed to and remain with the above-identified small business concern, or if the rights are not exclusive, then on information and belief, all other rights belong to the following entities, which also on information and belief are small entities as defined in 37 C.F.R. 1.9:

None.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

1/12/2000
Date

Tom Stitt
Signature

Member
Title

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1 DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM

2

3

Background of the Invention

4

5 Other than surgery, non-invasive manipulation, and
6 nutrition, the major means of treating diseases and medical
7 conditions is by the use of prescribed and over-the-counter
8 drugs. Drugs which can be harmful if misused or abused are
9 usually required by regulation to be prescribed by a
10 licensed physician and dispensed by a licensed pharmacist.

11 A prescription is conventionally a written order or
12 "script" by a physician identifying the medication to be
13 dispensed, the dosage, and the time interval at which the
14 dosage is to be taken, or applied in the case of a topical
15 drug. The identity of the drug may include the brand name
16 or its pharmaceutical equivalent. Dosage may include the
17 concentration or the weight of the tablet or capsule
18 containing the active ingredient and may include special
19 instructions, such as before or after meals, before bedtime,
20 or the like. A total number of dosage units is sometimes
21 factored into the dosage for a given medication. In
22 general, prescriptions are intended to achieve and maintain
23 a desired concentration of a drug within a patient for a
24 selected length of time to treat a medical condition.

1 One problem with the conventional manner of
2 prescriptions is that they are handwritten on a slip of
3 paper. Although errors in filling prescriptions because of
4 legibility problems are rare, they can occur with
5 potentially serious consequences. A conscientious
6 pharmacist will call the prescribing physician if there are
7 any doubts about the prescription script. Another potential
8 problem is that prescriptions can be counterfeited by use of
9 a physician's prescription forms. This usually occurs only
10 with drugs having an abuse or addiction potential. Another
11 problem is that the benefit of a prescribed drug can be
12 diminished if the patient does not follow the prescribed
13 schedule in taking it.

14 Electronic prescription reminder devices which are
15 programmed with the prescription schedule of one or more
16 drugs are known. Such a device sounds an alarm when it is
17 time to take a medication according to the schedule. Also
18 known are devices which record compliance by the patient in
19 taking a prescription. However, the problems in clearly
20 conveying the prescription information to the pharmacist and
21 prevention of counterfeiting or tampering with prescriptions
22 are not addressed by these devices.

23

1 Summary of the Invention

2

3 The present invention provides a method and a

4 prescription carrier apparatus for storing prescription data

5 by a physician and for retrieval by a pharmacist. The

6 carrier data cannot be accessed by the patient; however, the

7 carrier also functions as a prescription reminder for the

8 patient and as a prescription compliance recorder.

9 The prescription carrier is a device roughly the size

10 of a paging receiver or pager and has a dot matrix liquid

11 crystal display (LCD), an infrared (IR) communications

12 interface, pushbutton keys, a sound alert, and a vibration

13 alert. Internally, the carrier includes a microprocessor,

14 non-volatile memory, a real-time clock/calendar, and

15 interface circuitry to the LCD display, the IR

16 transmit/receive devices, the keys, and the alert devices.

17 Data access to the prescription carrier is made by way

18 of the IR interface which includes IR receiver and

19 transmitter devices. Such IR interfaces are provided on

20 some laptop computers for communication functions, such as

21 conveying data to be printed to a printer without electrical

22 connection of the laptop to the printer. The IR interface

23 provides for communication with a physician's computer or a

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1 pharmacist's computer, both of which are provided with
2 appropriate software to respectively upload or download
3 prescription and/or compliance data. The prescription data
4 may be in the form of a data record with data fields which
5 can be parsed by software within the prescription carrier to
6 retrieve the name of the medication along with dosage
7 factors and dosage scheduling. The processor within the
8 carrier uses the dosage scheduling data to set up a
9 prescription reminder schedule for each medication in
10 cooperation with the real time clock/calendar and the alert
11 devices. By this means, the carrier alerts the patient each
12 time a dose of the prescription medication is due.

13 The prescription carrier includes a "delay" switch and
14 a "take" switch. The delay switch functions similar to a
15 "snooze" button on a conventional alarm clock. It initiates
16 a delay clock function to alert again at the end of a delay
17 period, for example, of ten or fifteen minutes. Some
18 prescriptions may not allow delays in taking a dose. The
19 take switch is operated when the patient takes a medication
20 upon being alerted to do so and also deactivates the alert
21 device. While operation of the delay switch is not
22 generally recorded, operation of the take switch is recorded
23 as a "compliance" with the prescription. Each compliance

1 record may include the identity of the medication and the
2 time and date that the take switch was operated. The
3 compliance data can be downloaded by the prescribing
4 physician to compare treatment progress with prescription
5 compliance or to simply determine if the patient has or has
6 not been taking the medication as prescribed.

7 Because allowing the patient access to data within the
8 prescription carrier could result in obvious problems, such
9 access is restricted to the prescribing physician and the
10 pharmacist, or their employees. Access can be restricted by
11 the use of simple passwords. However, the data within the
12 prescription carrier of the present invention is preferably
13 encrypted using one or more encryption keys or digital
14 signatures which are available only to the physician and the
15 pharmacist, but not to the patient. The sciences of
16 effective techniques for encryption of digital data and
17 encryption keys for decrypting are well developed.
18 Background information on such encryption and digital
19 signature techniques can be obtained from U. S. Patent Nos.
20 4,200,770 and 5,537,475, which are incorporated herein by
21 reference. If the present invention, digital signatures
22 incorporating license numbers issued by the U. S. Drug
23 Enforcement Agency (DEA) are preferred.

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1 Objects and Advantages of the Invention

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3 The principal objects of the present invention are: to
4 provide an improved method and apparatus for conveying a
5 prescription medication from a physician to a patient; to
6 provide such a system including a portable prescription
7 carrier apparatus in which data representing the
8 prescription is uploaded by a physician and downloaded by a
9 pharmacist to fill the prescription; to provide such a
10 prescription carrier apparatus including circuitry and logic
11 which is programmable with prescription data including a
12 prescription schedule for alerting a patient when a dose of
13 a medication is due; to provide such a carrier apparatus
14 which is operable to record compliance of the patient with
15 the prescription for subsequent downloading and analysis by
16 the prescribing physician; to provide such a carrier
17 apparatus which is similar in size and shape to a pager
18 receiver and which includes both sonic and vibratory alert
19 devices; to provide such a carrier apparatus in which
20 prescription data therein is encrypted and which cannot be
21 decrypted by the patient to thereby prevent falsification or
22 counterfeiting of the prescription data therein; and to
23 provide such a digital prescription carrier and monitor

1 system which is economical to manufacture, which is precise
2 and effective in use, and which is particularly well adapted
3 for its intended purpose.

4 Other objects and advantages of this invention will
5 become apparent from the following description taken in
6 conjunction with the accompanying drawings wherein are set
7 forth, by way of illustration and example, certain
8 embodiments of this invention.

9 The drawings constitute a part of this specification
10 and include exemplary embodiments of the present invention
11 and illustrate various objects and features thereof.

12

13 Brief Description of the Drawings

14

15 Fig. 1 is a front elevational view of a digital
16 prescription carrier and monitor system which embodies the
17 present invention.

18 Fig. 2 is a block diagram illustrating the principal
19 circuit components of the digital prescription carrier and
20 monitor system.

21 Fig. 3 is a flow diagram illustrating the principal
22 software components of the system.

23

Variable	Mean	SD	Min	Max
Age	34.5	10.2	21	55
Gender	1.2	0.4	1	2
Marital status	1.5	0.5	1	3
Education	12.5	1.5	9	16
Income	1.8	0.8	1	3
Occupation	1.5	0.5	1	3
Religion	1.2	0.4	1	2
Health status	1.5	0.5	1	3
Stress level	2.5	1.0	1	4
Life satisfaction	3.5	1.0	1	5
Resilience	4.5	1.0	1	5
Optimism	3.5	1.0	1	5
Gratitude	3.5	1.0	1	5
Forgiveness	3.5	1.0	1	5
Compassion	3.5	1.0	1	5
Kindness	3.5	1.0	1	5
Generosity	3.5	1.0	1	5
Patience	3.5	1.0	1	5
Humility	3.5	1.0	1	5
Modesty	3.5	1.0	1	5
Self-control	3.5	1.0	1	5
Discipline	3.5	1.0	1	5
Perseverance	3.5	1.0	1	5
Determination	3.5	1.0	1	5
Confidence	3.5	1.0	1	5
Trust	3.5	1.0	1	5
Hope	3.5	1.0	1	5
Love	3.5	1.0	1	5
Peace	3.5	1.0	1	5
Harmony	3.5	1.0	1	5
Unity	3.5	1.0	1	5
Cooperation	3.5	1.0	1	5
Teamwork	3.5	1.0	1	5
Collaboration	3.5	1.0	1	5
Partnership	3.5	1.0	1	5
Relationship	3.5	1.0	1	5
Connection	3.5	1.0	1	5
Interaction	3.5	1.0	1	5
Engagement	3.5	1.0	1	5
Participation	3.5	1.0	1	5
Involvement	3.5	1.0	1	5
Contribution	3.5	1.0	1	5
Impact	3.5	1.0	1	5
Influence	3.5	1.0	1	5
Power	3.5	1.0	1	5
Authority	3.5	1.0	1	5
Leadership	3.5	1.0	1	5
Management	3.5	1.0	1	5
Organization	3.5	1.0	1	5
System	3.5	1.0	1	5
Structure	3.5	1.0	1	5
Process	3.5	1.0	1	5
Method	3.5	1.0	1	5
Technique	3.5	1.0	1	5
Strategy	3.5	1.0	1	5
Plan	3.5	1.0	1	5
Program	3.5	1.0	1	5
Project	3.5	1.0	1	5
Task	3.5	1.0	1	5
Job	3.5	1.0	1	5
Work	3.5	1.0	1	5
Activity	3.5	1.0	1	5
Behavior	3.5	1.0	1	5
Reaction	3.5	1.0	1	5
Response	3.5	1.0	1	5
Effect	3.5	1.0	1	5
Result	3.5	1.0	1	5
Outcome	3.5	1.0	1	5
Consequence	3.5	1.0	1	5
Impact	3.5	1.0	1	5
Influence	3.5	1.0	1	5
Power	3.5	1.0	1	5
Authority	3.5	1.0	1	5
Leadership	3.5	1.0	1	5
Management	3.5	1.0	1	5
Organization	3.5	1.0	1	5
System	3.5	1.0	1	5
Structure	3.5	1.0	1	5
Process	3.5	1.0	1	5
Method	3.5	1.0	1	5
Technique	3.5	1.0	1	5
Strategy	3.5	1.0	1	5
Plan	3.5	1.0	1	5
Program	3.5	1.0	1	5
Project	3.5	1.0	1	5
Task	3.5	1.0	1	5
Job	3.5	1.0	1	

13 Referring to the drawings in more detail:

8

1 The carrier 1 includes an outer housing 2 sized similar
2 to a pager and may include a resilient belt clip (not shown)
3 for wearing the carrier 1 on the belt of a patient or user.
4 The housing 2 includes a dot-matrix liquid crystal display
5 3, operation buttons 4, an alert device selection switch 5,
6 a sonic output device 6, and infrared interface link windows
7 7 and 8. The illustrated carrier 1 includes buttons for
8 scrolling up 14, scrolling down 15, delay 16, take 17, and
9 backlight toggle or light 18. The housing 2 also has a
10 battery (not shown) which powers circuitry 20 (Fig. 2)
11 therein through a low battery detector power supply 21.

12 The circuitry 20 includes a central processing unit or
13 CPU 24 which may be a microprocessor or microcontroller.
14 The processor 24 includes, among other on-chip components,
15 non-volatile RAM memory 26 and a real-time clock/calendar
16 27. Alternative to, or in addition to, the non-volatile RAM
17 26, the CPU 24 may include or be interfaced with read-only
18 memory (ROM) and/or conventional memory or RAM (neither
19 shown). Software 30 (Fig. 3) which operates within the
20 carrier 1 is stored in the non-volatile RAM 26.

21 The operation buttons or switches 4 are interfaced to
22 the CPU 24, as is the LCD display 3. LCD driver circuitry
23 32 interfaces the display circuitry 3 to the CPU 24.

1 Preferably, the display 3 is a dot-matrix type which
 2 provides greater flexibility of characters which can be
 3 displayed thereon than, for example, 7-segment type
 4 displays. The illustrated display 3 may, for example, be a
 5 commonly available 16 character by 2 line display. The
 6 illustrated carrier 1 includes the scroll buttons 14 and 15,
 7 the delay switch 16, the take switch 17, the backlight
 8 switch 18, and the alert select switch 5. However, it is
 9 foreseen that other user-selected functions may be desirable
 10 in the carrier 1, such that the carrier 1 is not intended to
 11 be limited only to the switches shown. The backlight switch
 12 18 toggles one or more light emitting diodes or LED's (not
 13 shown) which illuminate the display 3 to facilitate reading
 14 the display in darkness. Although the display 3 is
 15 preferably formed using liquid crystal display technology
 16 because of its low power consumption and ready availability,
 17 other display technologies could alternatively be employed.

18 The carrier 1 is provided with the sonic alert device 6
 19 to remind the user that it is time for a dose of a
 20 medication, the schedule for which is being tracked by the
 21 carrier 1. The sonic alert device 6 may be a small
 22 loudspeaker or other audio transducer capable of generating
 23 an acoustic signal. The device 6 is powered by sonic drive

1 circuitry 36 and interfaced to the CPU 24 thereby. The
2 sonic drive circuitry 36 may simply be a power amplifier or
3 may incorporate other elements. The carrier 1 is also
4 preferably provided with a vibrating alert device 38 in
5 cooperation with vibrator drive circuitry 40. Such
6 vibrating alert devices are common in paging receivers and
7 generate a tactile vibration when activated. The alert mode
8 selection switch 5 enables the user to select either the
9 sonic alert 6, the vibrating alert 38, or both. Although
10 not illustrated, it is also foreseen that the carrier 1
11 could be provided with a flashing lamp as an alternative
12 alert device for hearing impaired persons, although such
13 persons would still benefit from the vibrating alert 38.

14 The carrier 1 includes a communication port 42 for
15 interfacing the carrier 1 to an external computer or PC
16 system 44. Such a communication port 42 could be a
17 conventional RS-232 serial port or a more recent
18 communication interface such as a universal serial bus (USB)
19 interface, a "Firewire" (trademark of Apple Computer, Inc.)
20 interface, or the like. In the illustrated carrier 1, the
21 communication port 42 is an infrared (IR) data link 46
22 including a transmitter (TX) channel 48 and a receiver (RX)
23 channel 50. Such IR links 46 are provided on some laptop

1 computers, as well as on some peripheral devices, such as
2 printers, so that a document can be printed from the laptop
3 computer by the printer without a conductive connection. In
4 the carrier 1, the IR port 46 is used to upload a
5 prescription data into the carrier 1 and to download such
6 data from the carrier 1.

7 Fig. 3 illustrates the principal functions of the
8 software 30 which is executed by the CPU 24 of the carrier
9 1. In general, the carrier 1 is able to track the schedules
10 for a plurality of medications, the number of which is
11 limited by the size of the RAM 26, in cooperation with the
12 real-time clock/calendar 27. When a dose of a medication is
13 due, one or both of the alert devices 6 and/or 38 is
14 activated. The user of the carrier 1 can review the
15 upcoming medication schedule on the display 3 using the
16 scroll keys 14 and 15. The prescription data is entered
17 into the carrier 1 from an external computer 44 and accessed
18 to fill the prescriptions by way of the IR data link 46.
19 The external computer 44 executes special software (not
20 detailed herein) to access the carrier 1.

21 Referring particularly to Fig. 3, from the start
22 function 52, when a new battery (not shown) is installed in
23 the carrier 1, a main loop 53 is entered. The main loop 53

1 operated, at 61, the alert device 6/38 is deactivated,
2 operation of the take switch 17 is recorded, at 62, as a
3 "compliance" with the prescription, and the time of
4 compliance is recorded by the CPU 24 in the RAM 26. After
5 recording compliance at 62, the CPU 24 returns to the mode
6 test 54.

7 When the IR data link 46 is activated at 57, a
8 communication test is run at 64. If a communication link
9 has not been established with an external computer 44 by the
10 end of the wait interval, the IR data link 46 is deactivated
11 and control is returned to the mode test 54. If
12 communications have been established at 64, a security test
13 65 is entered, requiring the entry of a valid encryption key
14 or a password. If the entered encryption key or password is
15 not correct, communication between the carrier 1 and the
16 external computer 44 is disabled at 66 and control is passed
17 to the mode test 54.

18 If the encryption key or password is valid, a
19 communication mode test 67 is conducted to determine if a
20 pharmacy mode 68 or a doctor mode 69 is to be entered. In
21 the pharmacy mode 68, the pharmacist is allowed to access
22 all the current prescriptions, to decrement refill counts of
23 certain prescriptions, and to view patient information which

1 is stored in the carrier 1. The doctor mode 69 includes all
2 pharmacy mode privileges and additionally allows entry and
3 deletion of prescriptions, entry or update of patient
4 information, and access to prescription compliance data.

5 Most states still require the presentation of a
6 prescription form signed by a physician for certain
7 medications, especially those with a high potential for
8 abuse. Prescriptions for other drugs may be "called in".
9 The carrier 1 has utility as a sole prescription carrier or
10 as a digital version of a conventional signed prescription
11 form. The digital prescription data stored in the carrier 1
12 can be uploaded into the pharmacy computer system for
13 inventory control purposes, as well as to reduce data entry
14 errors and for cross-checking purposes. Thus, the carrier 1
15 of the present invention complements the functions of
16 current paper based methods of filling prescriptions rather
17 than simply replacing or duplicating such functions. The
18 carrier 1 also has a reminder function and a compliance
19 recording functions. The data link 46 gives the carrier 1
20 the capability of being accessed remotely, for example over
21 the internet, for the entry or modification of prescriptions
22 by the physician or review of the prescriptions or
23 compliance data by the physician or pharmacist.

1 It is to be understood that while certain forms of the
2 present invention have been illustrated and described
3 herein, it is not to be limited to the specific forms or
4 arrangement of parts described and shown.
5

C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. A method for conveying a prescribed medication to a patient and comprising the steps of:
 - (a) providing a digital prescription carrier including a read/write memory and a communication interface;
 - (b) uploading prescription data defining a prescription into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;
 - (c) transferring said carrier by a patient to a pharmacy;
 - (d) downloading said prescription data from said carrier through said interface at said pharmacy; and
 - (e) filling said prescription at said pharmacy.

2. A method as set forth in Claim 1 and including the step of:

- (a) entering an access code into said carrier to enable access to said prescription data prior to said uploading and downloading steps.

3. A method as set forth in Claim 1 and including the steps of:

- (a) operating a digital clock/calendar within said carrier to generate internal values of time and date;
- (b) providing said carrier with a prescription compliance switch interfaced to said clock/calendar;
- (c) operating said compliance switch by a patient upon taking a medication specified by said prescription; and
- (d) storing in a compliance memory within said carrier respective values of time and date occurring upon operation of said compliance switch.

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4. A method as set forth in Claim 3 and including the steps of:
 - (a) providing said carrier with an annunciator element;
 - (b) entering into said carrier by said pharmacist schedule data defining a prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by said prescription;
 - (c) periodically comparing within said carrier said internal values of time and date with said schedule times and dates; and
 - (d) activating said annunciator element upon said internal values of time and date matching a set of said schedule time and schedule date.

5. A method as set forth in Claim 1 wherein said step of providing said prescription carrier having a communication interface includes the step of:
 - (a) providing said prescription carrier with an infrared data communication interface.

6. A method as set forth in Claim 1 and including the steps of:

- (a) uploading prescription data defining a plurality of prescriptions for a plurality of medications into said carrier through said interface;
- (b) downloading said prescription data through said interface; and
- (c) filling each of said prescriptions defined by said prescription data.

7. A method for conveying a prescribed medication to a patient and comprising the steps of:
- (a) providing a digital prescription carrier including a read/write memory and a communication interface;
 - (b) entering a first access code into said carrier to enable software access thereto;
 - (c) uploading, subsequent to entering said an access code, prescription data defining a prescription into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;
 - (d) transferring said carrier by a patient to a pharmacy;
 - (e) entering a second access code into said carrier to enable software access thereto;
 - (f) downloading said prescription data from said carrier through said interface at said pharmacy subsequent to entering said second access code; and
 - (g) filling said prescription by said pharmacist.

8. A method as set forth in Claim 7 and including the steps of:

- (a) operating a digital clock/calendar within said carrier to generate internal values of time and date;
- (b) providing said carrier with a prescription compliance switch interfaced to said clock/calendar;
- (c) operating said compliance switch by a patient upon taking a medication specified by said prescription; and
- (d) storing in a compliance memory within said carrier respective values of time and date occurring upon operation of said compliance switch.

9. A method as set forth in Claim 8 and including the steps of:
- (a) providing said carrier with an annunciator element;
 - (b) entering into said carrier by said pharmacist schedule data defining a prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by said prescription;
 - (c) periodically comparing within said carrier said internal values of time and date with said schedule times and dates; and
 - (d) activating said annunciator element upon said internal values of time and date matching a set of said schedule time and schedule date.
10. A method as set forth in Claim 9 wherein said step of providing said carrier with an annunciator element includes the step of:
- (a) providing said carrier with a vibrating annunciator element.

11. A method as set forth in Claim 7 wherein said step of providing said prescription carrier having a communication interface includes the step of:

- (a) providing said prescription carrier with an infrared data communication interface.

12. A method as set forth in Claim 7 and including the steps of:

- (a) uploading, by a physician, prescription data defining a plurality of prescriptions for a plurality of medications to be taken on a plurality of schedules into said carrier through said interface;
- (b) downloading, by a pharmacist, said prescription data through said interface; and
- (c) filling each of said prescriptions defined by said prescription data.

13. A method as set forth in Claim 12 and including the steps of:

- (a) providing said carrier with an annunciator element;
- (b) entering into said carrier, by said pharmacist for each of said prescriptions, schedule data defining a respective prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by the respective prescription;
- (c) periodically comparing within said carrier said internal values of time and date with said schedule times and dates; and
- (d) activating said annunciator element upon said internal values of time and date matching a set of said schedule time and schedule date.

14. A digital prescription carrier apparatus comprising:
- (a) a carrier housing;
 - (b) a central processing unit (CPU) positioned within said housing;
 - (c) a display device positioned on said housing, interfaced to said CPU, and capable of displaying alphanumeric characters;
 - (d) input/output (I/O) interface circuitry positioned in said housing and interfaced to said CPU, said I/O circuitry being capable of interfacing said CPU to an external computer to exchange data therewith;
 - (e) data memory circuitry positioned within said housing; and
 - (f) prescription software stored in said memory to be processed by said CPU to enable, in cooperation with said I/O circuitry, uploading of prescription data representing a prescription into said memory circuitry at a physician's and downloading of said prescription data at a pharmacy.

15. An apparatus as set forth in Claim 14 and including:
- (a) a real-time clock/calendar positioned within said housing and interfaced to said CPU;
 - (b) an alert device positioned within said housing and interfaced to said CPU; and
 - (c) said prescription software cooperating with said prescription data, said clock/calendar, and said alert device to cause activation of said alert device when a dose of a medication prescribed by said prescription data is to be taken.
16. An apparatus as set forth in Claim 15 and including:
- (a) a compliance switch positioned on said housing and interfaced to said CPU; and
 - (b) said prescription software cooperating with said compliance switch to record in said data memory circuitry an occurrence of the operation of said compliance switch subsequent to activation of said alert device.

17. An apparatus as set forth in Claim 15 wherein said alert device includes:
- (a) a sonic alert device interfaced to said CPU; and
 - (b) a vibrating alert device interfaced to said CPU.
18. An apparatus as set forth in Claim 14 and including:
- (a) a plurality of key switches positioned on said housing and interfaced to said CPU;
 - (b) said prescription software causing uploaded prescription data to generate a schedule of dose times for a medication represented by said prescription data; and
 - (c) operation of said key switches enabling review of said schedule of dose times for said medication in cooperation with said display device.
19. An apparatus as set forth in Claim 14 wherein:
- (a) said I/O interface circuitry includes circuit elements forming an infrared data link.

Abstract of the Disclosure

A digital prescription carrier and monitor system includes a pager sized carrier apparatus with an internal processor, a real-time clock/calendar, non-volatile memory, a communication port, a character display, and alert devices. Prescription data for one or more medications is stored within the carrier by a physician and downloaded by a pharmacist to fill the prescriptions called for. The carrier apparatus requires the entry of an decryption key to access prescription data within the carrier to prevent unauthorized access or tampering with the prescription data. The carrier apparatus also functions as a prescription reminder to the patient and records compliance with the prescription, since a switch must be operated to quiet an alert device activated when a scheduled medication dose is due.

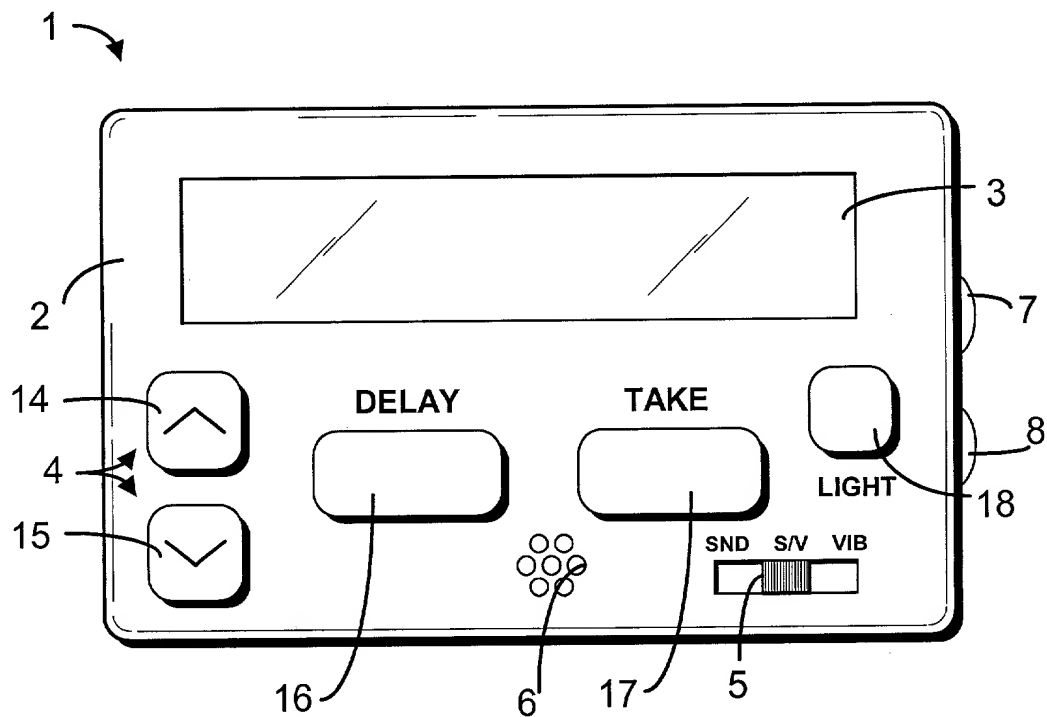


Fig. 1.

Fig. 2.

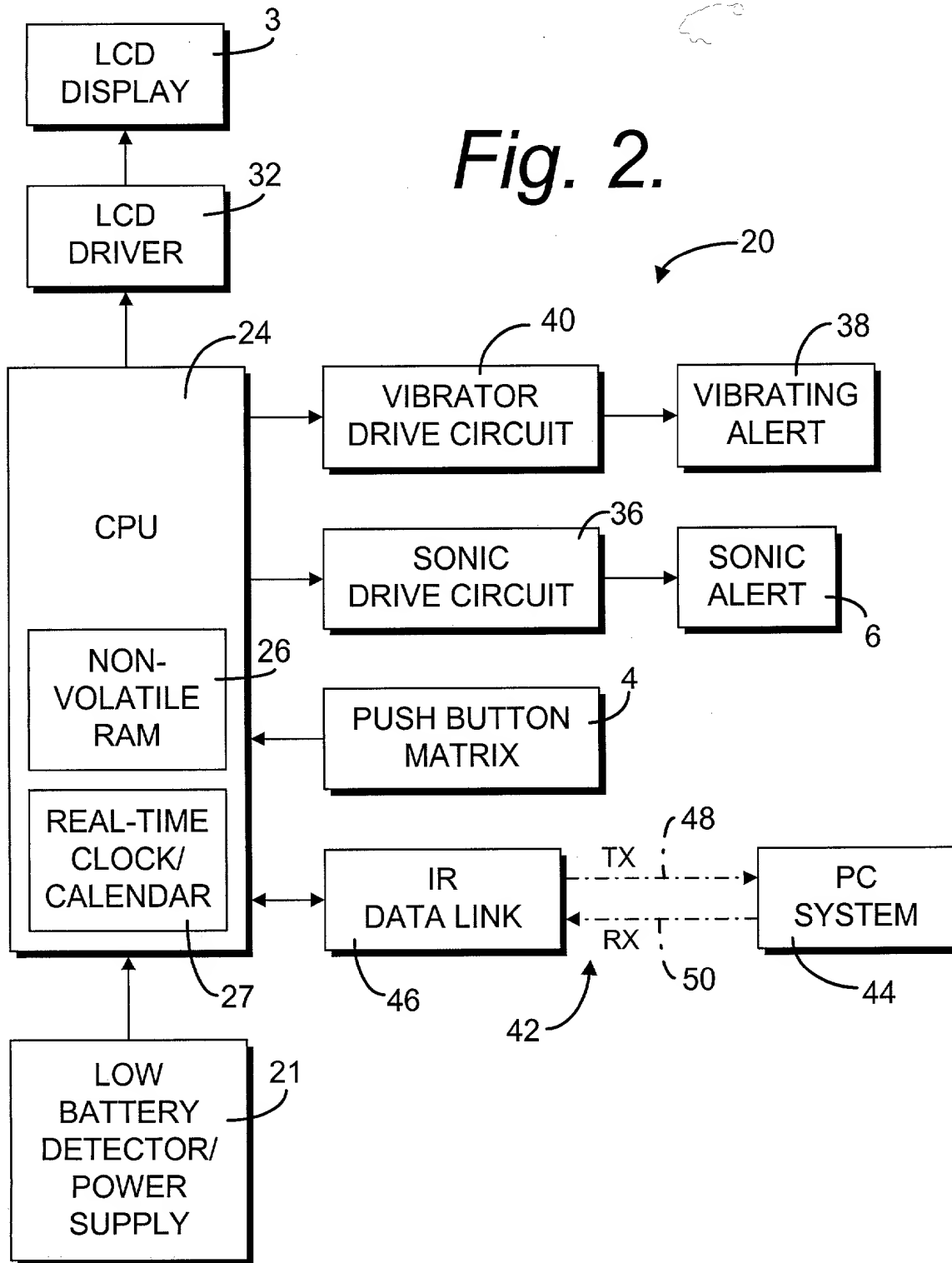
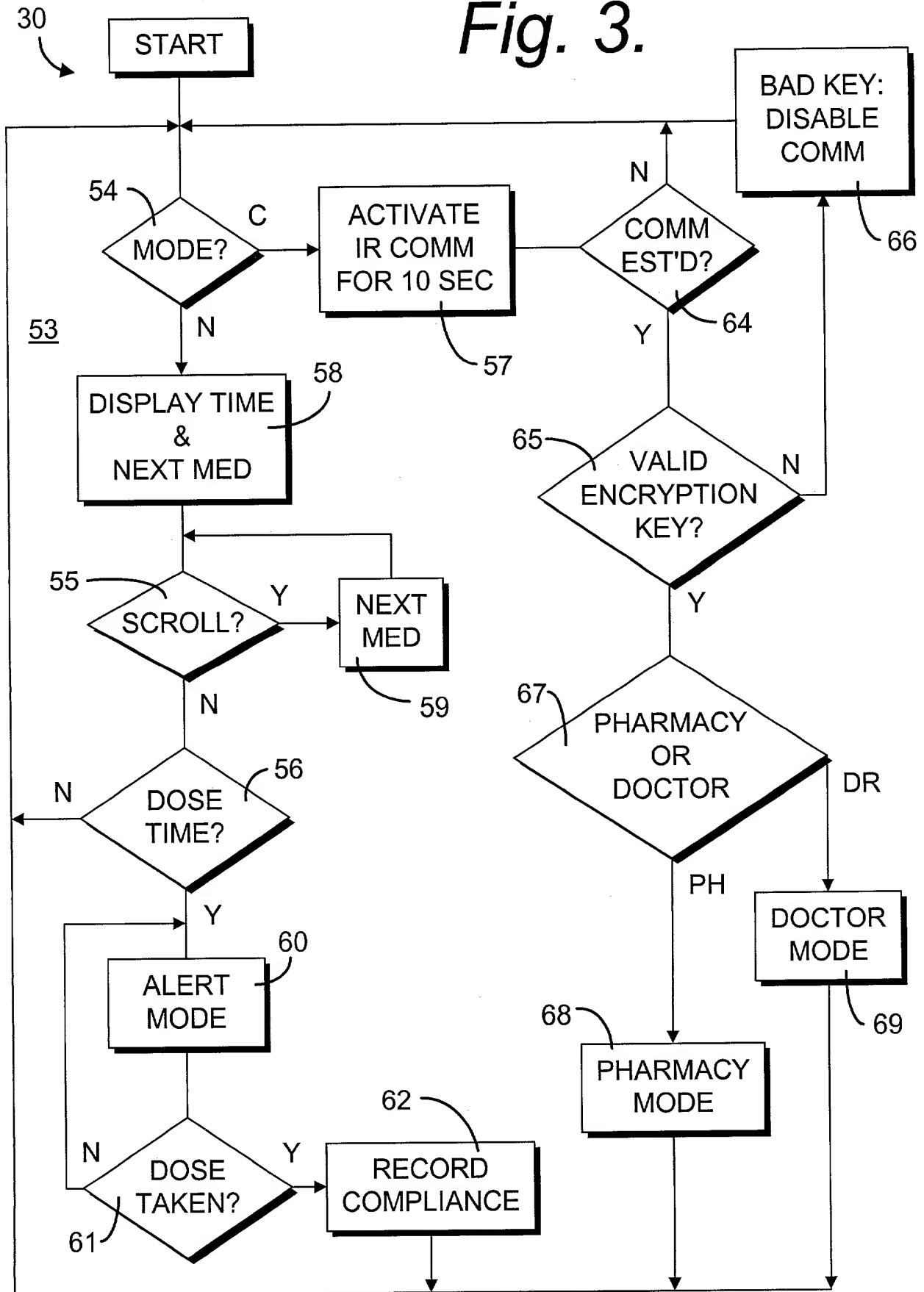


Fig. 3.



DECLARATION AND POWER OF ATTORNEY
FOR A PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM, the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Sec. 1.56. (Under Sec. 1.56 information is material to patentability when it is not cumulative to information already of record before the Patent and Trademark Office with respect to the present application and it establishes either by itself or in combination with other information a prima facie case of unpatentability of a claim or it refutes or is inconsistent with a position taken in opposing an argument of unpatentability relied upon by the Patent and Trademark Office or in asserting an argument of patentability. Under this section a prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and

before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.)

I hereby state that I do not know and do not believe that the invention was ever known or used in the United States of America before my invention thereof; that to the best of my knowledge and belief the invention has not been in public use or on sale in the United States of America more than one year prior to this application, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application, or patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application; and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns.

I hereby appoint Malcolm A. Litman, Reg. No. 19,579; Gerald M. Kraai, Reg. No. 34,854; Mark E. Brown, Reg. No. 30,361, and Kent R. Erickson, Reg. No. 36,793 , all members of the bar of the State of Missouri, whose postal address is Litman, Kraai & Brown, L.L.C., 4700 Belleview, Suite 200, Kansas City, Missouri 64112, telephone (816) 931-1800, as my attorneys, with full power of substitution, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the Patent Office connected therewith in my behalf.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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